

otherwise in condition for allowance. See page 2 of the Consent of Assignee Offer to Surrender Original Patent and Proof of Ownership Under 37 CFR §3.73(b).

Objection to Reissue Declaration

The Office stated that the reissue declaration is defective because the "declaration fails to state whether the inventor is the sole inventor of the invention as required by 37 CFR 1.63(a)(4)." See Office Action, page 2, lines 3-6. The Patent Owner respectfully traverses because the declaration did include the requested representation.

The relevant section of the Rules, §1.63(a)(4) states:

(a) An oath or declaration filed under §1.51(b)(2) as part of a nonprovisional application must:

(4) State that **the person making the oath or declaration believes the named inventor or inventors to be the first inventor or inventors of the subject matter which is claimed** and or which a patent is being sought.

In the Reissue Declaration Under 37 CFR §§ 1.172 and 1.175 (of Graham Edmund Kelly) submitted June 22, 2000, line number 2, states:

2. I [Graham Edmund Kelly] **believe I am the original and the first inventor of the subject matter that is being claimed** in U.S. Patent No. 5,830,887 ..."

Thus, the Reissue Declaration submitted clearly complies with 37 CFR §1.63(a)(4). The Patent Owner requests that the Office reconsider and withdraw the objection and the rejection of the claims based on the allegedly defective reissue declaration.

Ownership Interest

The Office has objected to the application under 37 CFR §1.172(a) because the "assignee has not established ownership interest in the patent." See Office Action, page 2, lines 13-24. The Examiner correctly notes that ownership interest may be established by submitting a chain of title and that the submission must be signed by a party authorized to act on behalf of the assignee.

The Patent Owner believes that the original submission meets these requirements. Specifically, the original submission included a Consent of Assignee to Surrender Original Patent, and Proof of Ownership Under 37 CFR §3.73(b) which stated that Novogen Research Pty Ltd. is the Assignee of the patent, and which submitted a chain of title demonstrating ownership interest. Specifically this chain of title includes the Assignment submitted April 13, 1998, assigning the application to Novogen Research Pty Ltd., together with the Petition for Entry of Late Assignment Papers, as well as the Decision by the Office of August 17, 1998, which granted the petition. There is no indication of reel or frame number because no Notice of Recordation of Assignment was ever sent by the Office in response to the April 13, 1998 submission. However, to facilitate prosecution, the Patent Owner is willing to resubmit the Assignment for recordation.

Thus, the ownership interest of assignee Novogen Research Pty Ltd., who is the assignee that appears on the face of U.S. Patent No. 5,830,887, has been established, and was submitted by an authorized agent. Therefore, the requirements of 37 CFR §1.172(a) are satisfied. Patent Owner requests reconsideration and withdrawal of the objection under 37 CFR §1.172.

Rejection Under 35 U.S.C. § 251

The Office has rejected claims 11-13 under 35 U.S.C. §251 as allegedly being an improper recapture of broadened subject matter. See Office Action, page 3, line 1 through page 5, line 4. The Patent Owner respectfully traverses. The Office is focusing on the initial recitation of the transition term "comprising" in the originally submitted "health supplement" claim and comparing that claim to the claim sought to be broadened here as the basis to find recapture. However, the claim at issue here recites "a pharmaceutical preparation" and that claim, as originally filed, actually recited the same the transition phrase as in claim 11, i.e.,

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“consisting essentially of.” Thus, the “pharmaceutical preparation” claim never recited the transition term “comprising,” and consequently the broadening coverage sought in this application was never previously sought. Accordingly, there cannot be any issue of recapture.

According to MPEP §1412.02, impermissible recapture exists when “the limitation now being omitted or broadened in the present reissue was originally presented/argued/stated in the original application to make the claims allowable over a rejection or objection made in the original application.” MPEP, Eighth Edition, page 1400-13, second column, fourth paragraph. Also note MPEP, Eighth Edition, page 1400-14, first Example, second paragraph, stating that “[t]he argument that the claim limitation defined over the rejection **must have been specific as to the limitation,**” meaning that there must be a clear statement that the limitation was presented to overcome the rejection.

Neither of these elements of improper recapture can be met here. First, as briefly noted above, no amendment was ever presented, argued, or stated changing the language “comprising” in a claim to “consisting essentially of” in either the health supplement claims or the pharmaceutical preparation claims. Second, even if the Examiner were to believe that an amendment had been made, there is no evidence that such a change was made to make the claims allowable over a rejection or objection made in the original application. Finally, in the entire prosecution history there is no statement, suggestion, or intimation that the limitation “consisting essentially of” in the pharmaceutical preparation claims was made in order to overcome any rejection or objection.

Looking now at the specifics of the prosecution history, the Office is correct that the initially filed composition claim 1 recited:

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1. A health supplement **comprising** a health supplementary amount . . .

See Preliminary Amendment filed November 21, 1994. However, as noted above, this composition claim was expressly directed to “a health supplement,” and not the pharmaceutical preparation claims now at issue.

The Office is also correct that the initially filed composition claim 1 had been rejected under 35 U.S.C. §103 as allegedly obvious in view of U.S. Patent No. 4,366,082 to Zilliken. *See* Office Action mailed September 10, 1996, page 10, line 16 through page 11. Specifically, the Examiner stated that Zilliken taught that the class of compounds claimed were effective antioxidants. *See id.*, page 11, lines 9-11. The Patent Owner notes that, in this rejection, the Examiner made no mention of the scope of the claim with regard to the language “comprising” or “consisting essentially of.”

Claim 1 was cancelled and replaced by claim 29 which, as the Office correctly notes, also recited a health supplement composition “comprising.” In an interview summary from February 19, 1997 that addressed claim 29, there was similarly no reference to the scope of the claim in terms of the transition phrases:

Composition claim 29 as proposed in draft of 02/18/97 would include term “natural” (see page 14 of specification re natural products) and Method claim 30 eliminates terms “or prevention” and “cancer of the bowel” and inserts in place of “at risk” the phrase “clinically predisposed to said conditions.” ...

The first “pharmaceutical preparation” claim was submitted as claim 36 on February 28, 1997, and it recited the transition term “consisting essentially of.” *See* Amendment and Request for Reconsideration, February 28, 1997, pages 1-2. In introducing the pharmaceutical preparation claims, the applicants noted that “New claims 36-38 are directed to a particularly preferred embodiment of the invention which was discussed at the February 19, 1997 interview.”

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Id. at page. 5. Thus, the pharmaceutical preparation claim 36 was not submitted as replacements for the health supplement claim 29.

The same amendment addressed the rejection of the health supplement claims under §103 with regard to antioxidant properties of tempeh. See Amendment of February 28, 1997, page 9, lines 17-31. The amendment also addressed whether Zilliken discloses Genistein and Diadzein, whether they are recoverable from tempeh, and whether only isoflavone derivatives are disclosed. *Id.*, page 9, line 32 through page 10, line 25. Finally, the amendment addressed Zilliken's failure to suggest ratios, dosage amounts, and forms. *Id.*, page 10, lines 26-29. There was no discussion about the scope of the health supplement claims with regard to the language "comprising." Further, no actual amendment has been argued, stated, or presented changing any language from "comprising" to "consisting essentially of."

In an interview with the Examiner on May 1, 1997, the Examiner stated that:

Amendments suggest by the Examiner and Attorney include cancellation of composition claims 2, 3, 5-9, 21, 22, 33, 34, and 36-38. Claim 30 Amended to remove references to Menopause and PMS, as methods limited to treatment of conditions not mentioned in prior art.

See Examiner Interview Summary Record of May 1, 1997. Interestingly, the health supplement claim 29, with its comprising language, was not even suggested for cancellation.

However, the Examiner did suggest the cancellation of pharmaceutical preparation claim 36, and applicants cancelled claim 36 and substituted for it claim 40. Like claim 36, claim 40 did not recite "comprising." Indeed, it recited the most narrow of transition phrases, "consisting of." The other differences between claim 36 and 40 are indicated by underlining in the following:

40. A pharmaceutical preparation, in solid dosage unit form, the biologically active component of said preparation consisting of any two or more concentrated, phytoestrogen-

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derived isoflavones selected from the group consisting of Genistein, Daidzein, Biochanin A, Formononetin, or the natural glycosides of any of said phytoestrogens and said preparation including a pharmaceutically acceptable carrier.

Claim 40 became present claim 11, but, as noted above, the Examiner added the word “essentially” to change the transition phrase to the broader “consisting essentially of.” Ultimately, claim 29 was cancelled in the Examiner’s Amendment accompanying the Notice of Allowability. Nonetheless, in this prosecution, no rejection was ever based on the scope of either of claims 29 or 36 or 40 with regard to the language “comprising” or “consisting essentially of” or “consisting of.” Claims 1 and 29, drawn to health supplements, always contained the language “comprising.” Claims 36 and 40, drawn to pharmaceutical preparations, were not drafted as replacements for claims 1 or 29, and claims 36 and 40 never contained the language “comprising.” Thus, no amendment was ever made changing “comprising” to “consisting essentially of.” Indeed, no rejections or objections to the language “comprising” were made over which an amendment could be made to traverse.

Even if the Examiner believes that such an amendment was made, the limitation “consisting essentially of” in claim 11 of U.S. Patent 5,830,887 was not added to make the claim allowable over a rejection or objection. None of the pharmaceutical preparation claims were rejected on the grounds of scope. Finally, MPEP, Eighth Edition, page 1400-14, first Example, second paragraph, states that “[t]he argument that the claim limitation defined over the rejection must have been specific as to the limitation,” meaning that there must be a clear statement that the limitation was presented to overcome the rejection. As set forth above, the transition term, and the scope that it conveyed, was never an issue in the prosecution, in either the health supplement claims or the pharmaceutical preparation claims.

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Thus, for all the foregoing reasons, no impermissible recapture exists. Accordingly, the Patent Owner requests reconsideration and withdrawal of the rejection under 35 U.S.C. §251.

Thus, the Patent Owner requests reconsideration and timely allowance of all pending claims. If the Examiner does not find that this Response puts the claims in condition for allowance, the Patent Owner requests that the Examiner contact the undersigned at (650) 849-6676 to arrange a telephone interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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